* Required by ClinicalTrials.gov

ClinicalTrials.gov Basic Results Data Element

1. Results Point of Contact*
- **Name or Official Title***
- **Organization Name***
- **Phone*** (or Email)
- **Email*** (or Phone)

2. Certain Agreements*
- **Is PI an Employee of Sponsor? (Y/N)***
  - **Results Disclosure Restrictions on PI? (Y/N)***
  - **PI Disclosure Restriction Type***

3. Participant Flow*
- **Recruitment Details**
- **Pre-assignment Details**
- **Arm/Group***
  - **Arm/Group Title***
  - **Arm/Group Description**
- **Period(s)***
  - **Period Title***
  - **Milestone(s)***
    - **STARTED***
    - **COMPLETED***
    - **[Not Completed] (calculated)**
    - **Additional Milestone(s)**
      - **Milestone Title***
      - **Milestone Data***
        - **Number***
        - **Comments**
    - **Drop/Withdraw Reason**
      - **Drop Reason Type***
        - **Other Reason***
      - **Drop/Withdraw Reason Data***

4. Baseline Characteristics*
- **Arm/Group***
  - **Arm/Group Title***
  - **Arm/Group Description**
- **Baseline Measure(s)***
  - **Baseline Measure Type***
    - **Study-Specific Baseline Characteristic(s)***
  - **Measure Type***
    - **Measure of Dispersion ***
  - **Unit of Measure***
- **Category Title***
- **Baseline Characteristic Data***
  - **Number*** (if Applicable)
  - **Descriptive Statistics*** (if Applicable)
    - **Central Tendency Value**
    - **Dispersion Value(s)**

5. Outcome Measures*
Arm/Group*
Arm/Group Title*
Arm/Group Description
Number of Participants Analyzed*
Analysis Population Description
Outcome Measure*
Outcome Measure Type*
Outcome Measure Title*
Outcome Measure Time Frame*
Outcome Measure Description
Measure Type*
Measure of Dispersion*
Unit of Measure*
Category Title*
Outcome Data*
Number* (if Applicable)
Descriptive Statistics* (if Applicable)
Central Tendency Value
Dispersion Value
Statistical Analyses
Statistical Analysis Overview
Comparison Group Selection*
Comments
Non-inferiority or Equivalence Analysis? (Y/N)*
Comments
Statistical Test of Hypothesis
P-Value* (if Applicable)
Comments
Method* (required if "P-Value" is reported)
Other Method Name*
Comments
Method of Estimation
Confidence Interval* (if Applicable)
Level*
Lower Limit*
Upper Limit*
Estimated Value*
Estimation Parameter* (required if "Confidence Interval" is reported)
Other Parameter Name*
Dispersion of Confidence Interval
Parameter Dispersion Type
Amount of Dispersion
Comments
6. Overall Limitations and Caveats